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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/067,124	02/04/2002	Shigeru Oita	02070/HG	5979

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NEW YORK, NY 10017-2023

EXAMINER

FIELD, TAMMY K

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 04/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/067,124	OITA, SHIGERU	
	Examiner	Art Unit	
	Tammy K. Field	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-22 is/are pending in the application.
- 4a) Of the above claim(s) 14-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-13 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

NonFinal Action

Response to Amendment and Remarks

1. In view of Applicant's amendments received 12 December 2003 and upon further consideration, the Rejections of the Record are withdrawn.
2. Claims 1 and 3 have been amended, claim 2 canceled, and new claims 4-22 added.
3. Applicant's remarks on page 8 as to support for new claims 14-21 are noted. However, newly submitted claims 14-19 and claims 20-21 are directed to inventions that are independent or distinct from the invention originally claimed for the following reasons: New claims 14-19 are drawn to a method of sterilizing bacteria, a different class of invention, and New claims 20-21 are drawn to a food in combination with a bactericidal composition, a different composition.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 14-21 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

4. Upon careful review of Applicant's remarks, amended claims 1 and 3, and new claims 4-13 and 22 are respectfully considered supportive to applicant's original claims drawn to a bactericidal composition and therefore, claims 1 and 3-13 and 22 will be considered are presently under examination.

Priority

5. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy filed on February 4, 2002 is of record. However, for the Office to consider the priority date of August 22, 2001 of JP Application 2001-251048 an English translation is required.

Status of Claim Rejections - 35 USC § 103

6. Claims 1, 3-13, and 22 are rejected under 35 U.S.C. 103(a) as being obvious over

Oita, U.S. Pat. No. 6,329,011 in view of Wilhott, et al. U.S. Pat. No. 5,573,800.

The claims are drawn to a bactericidal composition comprising (a) at least one ethylenediaminetetraacetic acid (EDTA) and a metal sodium salt and (b) at least one alpha or beta thionin. Subsequent claims are drawn to EDTA/metal salt content, $\geq 0.05 \text{ mM} < 1.5 \text{ MM}$ and alpha/beta thionin content, $\geq 1 \text{ ug/ml} \leq 150 \text{ ug/ml}$ wherein the composition consists essentially of (a) and (b), and wherein EDTA salt is a disodium or tetrasodium salt.

Oita, S. teach a antimicrobial (inherently bactericidal) compositions consisting essentially of alpha or beta thionin ranging from 1ug/ml to 100 ug/ml in combination with the antimicrobial peptide of nisin at column 2, line 64-column 3, line 5 (also see Example I, Table 1).

Oita, S. do not teach compositions of thionin(s) in combination with an EDTA metal salt.

Wilhott, D.L. *et al.* teach bactericidal compositions consisting essentially of 0.8 wt. % NA_2EDTA at column 18, lines 30- 46. The limitation of claim 3 is considered as a limitation of optimizing experimental perimeters.

In the alternative, it would have been prima facie obvious to one having ordinary skill in the art at the time the invention was made to combine the ingredients of alpha or beta thionin of Oita, S. with the ingredients of NA_2EDTA of Wilhott, D.L. *et al.* in a bactericidal composition. Wilhott, D.L. *et al.* further teach surprisingly that the bacterial counts using the combination of NA_2EDTA and nisin greatly reduce bacteria viability when compared to either ingredient alone and thus, both NA_2EDTA and nisin appear to act synergistically to reduce the total number of

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bacteria (column 18, lines 31-47). Therefore, one of ordinary skill would have been motivated to combine the ingredients of alpha or beta thionin and NA_2EDTA to enhance the effects of a bactericidal composition because Oita, S. and Wilholt, D.L. *et al.* combined teach the bactericidal composition of the instant invention. It would have been expected, barring evidence to the contrary, that the combined use of NA_2EDTA and thionin in a bactericidal composition would be effective in controlling bacterial activity.

Thus, the teachings of Oita, S. and Wilholt, D.L. *et al.* combined render obvious the claimed invention.

7. Since the office does not have the facilities for examining and comparing applicants' detection and diagnosis methods with the methods disclosed in the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed method and the methods of the prior art (*i.e.* that the methods of the prior art does not possess the same material structural and functional characteristics of the claimed methods). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Status of Claims

8. No Claims allowed.

Conclusion

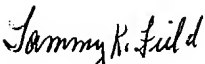
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tammy K. Field whose telephone number is (571) 272-0856. The examiner can normally be reached on Monday-Friday from 7am-4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached at (571) 272- 0864.


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Papers relating to this application may be submitted to Technology Center 1600 Group 1640 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 for regular communications and After Final communications.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov/>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Tammy K. Field

April 16, 2004


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